

## **REMARKS**

Applicants respectfully request entry of amendments to claims 1-4, 6-10, and 12-14, and new claim 40. Please cancel claims 5 and 11, and withdraw claims 15-39, without prejudice or disclaimer. Support for the amendments can be found throughout the specification, including paragraphs [0006], [0014], [0043], [0045], Table 3, the Sequence Listing, and the originally filed claims and, therefore, do not add new matter.

Applicants submit that pending claims 1-4, 6-10, 12-14, and 40 are in condition for allowance, and respectfully request that the claims as amended be entered.

### **Restriction Requirement**

Applicants wish to thank the Examiner for rejoining the primer pairs and acknowledging Applicants' request for rejoinder of process claims with an allowable product as required by M.P.E.P. §806.05(h).

### **Rejection Under 35 U.S.C. §112, Second Paragraph**

Claims 3-7 and 12 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. As claim 5 has been canceled, the rejection as applied to this claim is rendered moot.

Applicants have amended the claims, where appropriate, to recite "nucleic acid sequence." The term "sequence," which is what a sequence identifier denotes, is a term of art and would be known to one of skill in the biotechnology art, to which this invention belongs. As such, one of skill in the art would understand the metes and bounds of the claims.

For these reasons, Applicants respectfully request that the rejection be withdrawn.

Rejections Under 35 U.S.C. §102

Claims 1 and 2 stand rejected under 35 U.S.C. §102(b), as allegedly being anticipated by Bohne et al., Blais et al., or Camilli et al.

Applicants traverse the rejection as it might apply to the amended claims, including claims dependent therefrom, for the reasons given below.

The Office Action alleges, in pertinent part, that the cited references teach the elements as recited in the present claims, specifically, that the references teach virulence genes “*prfA*, *pclA*, *hyl*[sic], *mpl*, *plcB*, and *actA*.” The instant claims have been amended to recite a specific sequence identifier: i.e., SEQ ID NO: 9. Review of SEQ ID NO: 9 demonstrates that a contiguous reading frame is present within residues 887 to 1500, which delimit a target for PCR amplification using primers defined by SEQ ID NO:26 and SEQ ID NO:27. As a point of reference, the predicted amino acid sequence for this contiguous reading frame is given below:

“VTPLTQLTYFDCSVNPLTELDVSTLSKLTTLHCIQTDLLEIDLTHNTQLIYFQAEGCRKI  
KELDVTHNTQLYLLDCQAAGITELDLSQNPCLVYLYLNNTTELDVSHNTKLKSLSCVN  
AHIQDFSSVGKIPALNNNFEEAGQTITMPKETLTNNSLTIAVSPDLLDQFGNPMNIEPGD  
GGVYDQATNTITWENLSTDNPAV”

Review of the amino acid sequences available from the National Center for Biotechnology Information (NCBI) for the sequences recited in the Action (see, e.g., Exhibits A-F), show that no significant homology exists between the virulence genes recited in the Action and the predicted amino acid sequence from the contiguous reading frame present within SEQ ID NO: 9. Because the present claims expressly recite a sequence identifier, which is not taught or suggested in the references cited, neither Bohne et al., Blais et al., nor Camilli et al., separately or in combination, anticipate the claimed invention.

As stated in Hybritech Inc. v. Monoclonal Antibody, Inc., 231 U.S.P.Q. 81 (Fed. Cir. 1986), “It is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention.”

Therefore, because the instant claims recite a sequence identifier which is not taught or suggested in the references cited, the cited references, alone or in combination, do not anticipate the claimed invention.

Failure of the prior art to meet every element of the claimed invention does not meet the standard under §102. For these reasons, Applicants respectfully request that the rejection be withdrawn.

Claims 1-14 stand rejected under 35 U.S.C. §102(b), as allegedly being anticipated by Kunst et al. or Glasner et al. As Claims 5 and 12 have been canceled, the rejection as applied the these claims is rendered moot.

Applicants traverse the rejection as it might apply to the amended claims, including claims dependent therefrom, for the reasons given below.

The Office Action alleges, in pertinent part, that the cited references teaches the elements as recited in the present claims. Glasner et al. is offered to demonstrate the isolation of virulence genes “*prfA*, *pclA*, *hyl*[sic], *mpl*, *plcB*, and *actA*.” Again, as stated above, the instant claims have been amended to recite a specific sequence identifier: i.e., SEQ ID NO: 9. Review of SEQ ID NO:9 demonstrates that a contiguous reading frame is present within residues 887 to 1500, which delimit a target for PCR amplification using primers defined by SEQ ID NO:26 and SEQ ID NO:27. As a point of reference, the predicted amino acid sequence for this contiguous reading frame is given below:

“VTPLTQLTYFDCSVNPLTELDVSTLSKLTTLHCIQTDLLEIDLTHNTQLIYFQAEGCRKI  
KELDVTHNTQLYLLDCQAAGITELDLSQNPKL VYLYLNNTTELDVSHNTKLKSLSCVN

AHIQDFSSVGKIPALNNNFEEAGQTITMPKETLTNNSLTIAVSPDLLDQFGNPMNIEPGD  
GGVYDQATNTITWENLSTDNPAV”

Review of the amino acid sequences available from NCBI for the sequences recited in the Action (see, e.g., Exhibits A-F), show that no significant homology exists between the virulence genes recited in the Action and the predicted amino acid sequence from the contiguous reading frame present within SEQ ID NO: 9. Because the present claims expressly recite the sequence identifier, which is not taught or suggested in Glaser et al., the reference does not anticipate the claimed invention.

Regarding Kunst et al., the Office Action states that the claimed sequences, SEQ ID NO: 9, 26, and 27, are disclosed in the reference. While it is not clear as to which search report the Action is referring to in support of the statement that the sequence identifiers are disclosed, the Kunst et al. sequences can be obtained from the PTO website at, for example:

<http://seqdata.uspto.gov/?pageRequest=viewSequence&DocID=20040018514&seqID=2870>  
and

<http://seqdata.uspto.gov/?pageRequest=viewSequence&DocID=US20040018514A1&seqID=2909>.

Applicants submit that review of SEQ ID NO: 2909 and 2870 demonstrates that these sequences do not anticipate SEQ ID NO: 9, 26, or 27 as claimed.

Exhibits G and H represent the nucleic acid sequences denoted by sequence identifiers 2870 and 2909 of Kunst et al. At minimum, because both SEQ ID NO: 2870 and 2909 have fewer nucleotides than SEQ ID NO: 9 (2556/759 vs. 2640), SEQ ID NO: 2870 and 2909 are not identical to SEQ ID NO: 9, and thus, do not anticipate SEQ ID NO: 9 as claimed.

Further, Applicants submit that there is no teaching in Kunst et al. which would lead one of skill in the art to make the primers as recited. In the same fashion that genomes do not

inherently anticipate isolated structural genes for want of enablement, Kunst et al. do not provide sufficient guidance to specifically identify the primer sequences as claimed (see, e.g., Chester v. Miller, 15 U.S.P.Q.2d 1281 (Fed. Cir. 1990), where the court stated that “[t]o be prior art under section 102(b), the reference must put the anticipating subject matter at issue into the possession of the public through an enabling disclosure.”). Both SEQ ID NOS: 2870 (2556 nt) and 2909 (759 nt) are orders of magnitude longer than either SEQ ID NO: 26 (21 nt) or 27 (20 nt). And while Kunst et al. may or may not suggest the use of primers for the detection of *Listeria* contamination, there is no guidance which would direct the skilled artisan to choose the specific primers as claimed among all the possible alternative fragments that comprise SEQ ID NOS: 2870 and/or 2909.

As stated in Hybritech Inc. v. Monoclonal Antibody, Inc., 231 U.S.P.Q. 81 (Fed. Cir. 1986), “It is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention.”

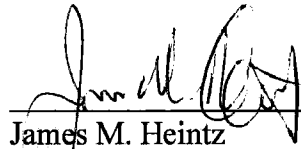
Therefore, because the instant claims a) recite a sequence identifier which is not taught or suggested in the cited references and b) recite specific primer sequences which would not be enabled by the teachings of the cited references, neither Glasner et al. nor Kunst et al. anticipate the claimed invention.

Failure of the prior art to meet every element of the claimed invention does not meet the standard under §102. For these reasons, Applicants respectfully request that the rejection be withdrawn.

In light of the above, Applicants submit that this application is now in condition for allowance and therefore request favorable consideration. If any issues remain which the Examiner feels may be best resolved through a personal or telephonic interview, the Examiner is respectfully requested to contact Applicants counsel, James M. Heintz at 202.861.4167.

Respectfully submitted,

DLA PIPER US LLP



A handwritten signature in black ink, appearing to read 'James M. Heintz', is written over a horizontal line.

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Daryl A. Basham, Ph.D.  
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# EXHIBIT A

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☐ 1: [CAA43524](#). Reports prfA [*Listeria mo...*[gi:48960]]

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[Sequence](#)

LOCUS CAA43524 237 aa linear BCT 12-JUN-2006  
 DEFINITION prfA [*Listeria monocytogenes*].  
 ACCESSION CAA43524  
 VERSION CAA43524.1 GI:48960  
 DBSOURCE embl accession [X61210.1](#)  
 KEYWORDS .  
 SOURCE *Listeria monocytogenes*  
 ORGANISM *Listeria monocytogenes*  
 Bacteria; Firmicutes; Bacillales; Listeriaceae; Listeria.  
 REFERENCE 1  
 AUTHORS Mengaud,J., Dramsi,S., Gouin,E., Vazquez-Boland,J.A., Milon,G. and Cossart,P.  
 TITLE Pleiotropic control of *Listeria monocytogenes* virulence factors by a gene that is autoregulated  
 JOURNAL Mol. Microbiol. 5 (9), 2273-2283 (1991)  
 PUBMED [1662763](#)  
 REFERENCE 2 (residues 1 to 237)  
 AUTHORS Dramsi,S., Kocks,C., Forestier,C. and Cossart,P.  
 TITLE Internalin-mediated invasion of epithelial cells by *Listeria monocytogenes* is regulated by the bacterial growth state, temperature and the pleiotropic activator prfA  
 JOURNAL Mol. Microbiol. 9 (5), 931-941 (1993)  
 PUBMED [7934921](#)  
 REFERENCE 3 (residues 1 to 237)  
 AUTHORS Cossart,P.F.  
 TITLE Direct Submission  
 JOURNAL Submitted (09-AUG-1991) P.F. Cossart, Inst Pasteur, Lab de Gen Mol des Listeria, 28 rue du DR. Roux, 75015 Paris, FRANCE  
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## ORIGIN




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Jan 29 2007 13:59 11

# EXHIBIT B

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☐ 1: [AAAY54619](#). Reports PlcA [*Listeria mo...*][gi:66737346]

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Features Sequence

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 ACCESSION [AAAY54619](#)  
 VERSION [AAAY54619.1](#) GI:66737346  
 DBSOURCE accession [DQ054593.1](#)  
 KEYWORDS .  
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 ORGANISM [Listeria monocytogenes](#)  
 Bacteria; Firmicutes; Bacillales; Listeriaceae; Listeria.  
 REFERENCE 1 (residues 1 to 269)  
 AUTHORS Jiang,L.L., Xu,J.J., Chen,N., Shuai,J.B. and Fang,W.H.  
 TITLE Virulence phenotyping and molecular characterization of a low-pathogenicity isolate of *Listeria monocytogenes* from cow's milk  
 JOURNAL *Acta Biochim. Biophys. Sin. (Shanghai)* 38 (4), 262-270 (2006)  
 PUBMED [16604266](#)  
 REFERENCE 2 (residues 1 to 269)  
 AUTHORS Jiang,L., Xu,J., Chen,N., Shuai,J. and Fang,W.  
 TITLE Direct Submission  
 JOURNAL Submitted (07-MAY-2005) Institute of Preventive Veterinary Medicine, College of Animal Science, 268 Kaixuan Road, Hangzhou, Zhejiang 310029, China  
 COMMENT Method: conceptual translation.  
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# EXHIBIT C

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 ACCESSION    AAY54621  
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 DBSOURCE     accession [DQ054595.1](#)  
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     ORGANISM   [Listeria monocytogenes](#)  
                  Bacteria; Firmicutes; Bacillales; Listeriaceae; Listeria.  
 REFERENCE    1 (residues 1 to 510)  
     AUTHORS    Jiang,L.L., Xu,J.J., Chen,N., Shuai,J.B. and Fang,W.H.  
     TITLE       Virulence phenotyping and molecular characterization of a  
                  low-pathogenicity isolate of *Listeria monocytogenes* from cow's milk  
     JOURNAL     Acta Biochim. Biophys. Sin. (Shanghai) 38 (4), 262-270 (2006)  
     PUBMED     [16604266](#)  
 REFERENCE    2 (residues 1 to 510)  
     AUTHORS    Jiang,L., Xu,J., Chen,N., Shuai,J. and Fang,W.  
     TITLE       Direct Submission  
     JOURNAL     Submitted (07-MAY-2005) Institute of Preventive Veterinary  
                  Medicine, College of Animal Science, 268 Kaixuan Road, Hangzhou,  
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481 kkalqqaakd lygedaskkv aeaweavgvn
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# EXHIBIT D



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☐ 1: [AAAY54609](#). Reports PlcB [*Listeria monocytogenes*] [gi:66737326]

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## Features Sequence

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 ACCESSION AAY54609  
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 DBSOURCE accession [DQ054583.1](#)  
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 ORGANISM *Listeria monocytogenes*  
 Bacteria; Firmicutes; Bacillales; Listeriaceae; Listeria.  
 REFERENCE 1 (residues 1 to 289)  
 AUTHORS Jiang,L.L., Xu,J.J., Chen,N., Shuai,J.B. and Fang,W.H.  
 TITLE Virulence phenotyping and molecular characterization of a low-pathogenicity isolate of *Listeria monocytogenes* from cow's milk  
 JOURNAL Acta Biochim. Biophys. Sin. (Shanghai) 38 (4), 262-270 (2006)  
 PUBMED [16604266](#)  
 REFERENCE 2 (residues 1 to 289)  
 AUTHORS Jiang,L., Xu,J., Chen,N., Shuai,J. and Fang,W.  
 TITLE Direct Submission  
 JOURNAL Submitted (07-MAY-2005) Institute of Preventive Veterinary Medicine, College of Animal Science, 268 Kaixuan Road, Hangzhou, Zhejiang 310029, China  
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// 241 ivnaktkksy lvgnsewkkd tveptgarlr dsqgtlagfl efwskktn

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# EXHIBIT E



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# EXHIBIT F



**Protein**
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 REFERENCE 1 (residues 1 to 277)  
 AUTHORS Ducey, T.F., Page, B., Usgaard, T., Borucki, M.K., Pupedis, K. and Ward, T.J.  
 TITLE A Single-Nucleotide-Polymorphism-Based Multilocus Genotyping Assay for Subtyping Lineage I Isolates of *Listeria monocytogenes*  
 JOURNAL Appl. Environ. Microbiol. 73 (1), 133-147 (2007)  
 PUBMED [17085705](#)  
 REFERENCE 2 (residues 1 to 277)  
 AUTHORS Ducey, T.F., Page, B., Usgaard, T., Borucki, M.K., Pupedis, K. and Ward, T.J.  
 TITLE Direct Submission  
 JOURNAL Submitted (22-JUN-2006) Microbial Genomics and Bioprocessing Research Unit, United States Department of Agriculture, Agricultural Research Service, 1815 N. University Street, Peoria, IL 61604, USA  
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